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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,260

05/04/2006

Noriaki Tanaka

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20529 7590 12/23/2008  
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EXAMINER

POPA, ILEANA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,260	<b>Applicant(s)</b> TANAKA ET AL.	
	<b>Examiner</b> ILEANA POPA	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claim 2 has been cancelled. Claims 1 and 3-6 have been amended.  
Claims 1 and 3-6 are pending and under examination.
2. All objections and rejections pertaining to claim 2 are moot because Applicant cancelled the claim in the reply filed on 10/08/2008.
3. Acknowledgment is made of Applicant's submission on 10/08/2008 of a written assurance indicating that the NAKT-13 cell line has been deposited under the Budapest Treaty with the International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology under the accession number FERM BP-08461 on September 4, 2003 and that the deposited cell line will be irrevocably and without restriction or condition released to the public upon the issuance of the patent.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

4. The rejection of claims 5 and 6 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn in response to Applicant's amendments to the claims filed on 10/08/2008.

#### ***Claim Rejections - 35 USC § 102***

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 3-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by de la Tour et al. (Molecular Endocrinology, 2001, 476-483), as evidenced by Halvorsen et al. (Molecular and Cellular Biology, 1999, 19: 1864-1870).

de la Tour et al. teach the reversibly immortalized  $\beta$ lox5 cell line derived according to the method of Halvorsen et al. by infecting human pancreatic  $\beta$ -cells with retroviral vectors expressing SV40T and hTERT (p. 477, column 1, first paragraph), wherein Halvorsen et al. teach that the SV40T and hTERT sequences used to obtain the  $\beta$ lox5 cell line contain *loxP* sites on each side (see Halvorsen et al., p. 1865, columns 1 and 2, Fig. 1); de la Tour et al. teach that the  $\beta$ lox5 cell line produces insulin after excision of the nucleic acid sequences encoding SV40T and hTERT (claim 1), i.e., they teach a human pancreatic islet cell obtained by excising the SV40T and hTERT genes and a method of producing insulin by using this cell (claims 3, 4, and 6) (p. 480, column 1 and Fig. 6). de la Tour et al. also teach that the immortalized  $\beta$ lox5 cell line can be induced to produce insulin, i.e., they teach a method of producing insulin by utilizing the immortalized  $\beta$ lox5 cell line (claim 5) (p. 477, column 2, p. 478, column 1). Since de la Tour et al. teach all claim limitations, the claimed invention is anticipated by the above-cited art.

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Applicant traversed the instant rejection on the grounds that the instant claims, as amended, is directed to the NAKT-13 cell line or a passage thereof, which is not taught by the cited references. Therefore, Applicant argues, the instant rejection is not anticipated by the cited art and the rejection should be withdrawn.

Applicant's arguments are acknowledged, however, the rejection is maintained because the claims encompass any passage of the NAKT-13 cell line. The art teaches that transformed cell lines (immortalized cell lines included) are not stable when passaged through subsequent generations, i.e., they lose their specific characteristics (see Richards, NeuroReport, 1999, 10: i). Because passages lose the characteristics which distinguish the NAKT-13 cells from the cells taught by the prior art and because the claims are drawn to such passages, the claimed invention is anticipated by the art cited above. For these reasons, the rejection is maintained.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph – new matter***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

As amended, the instant claims encompass obtaining the NAKT-13 cell line with any vector encoding hTERT and SV40T. Applicants point to page 16, lines 8-13 for support. It is noted that the indicated passage does recite establishment of the NAKT-13 cell line by transducing pancreatic cells with the retroviral vectors SSR#69 and 197. The specification does not provide support for obtaining the NAKT-13 cell line with just any vector encoding hTERT and SV40T. A search of the remaining portions of the specification failed to provide literal support for obtaining the NAKT-13 cell line with any vector encoding hTERT and SV40T.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often

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necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Richards (NeuroReport, 1999, 10: i) was cited to evidence that immortalized cell lines lose their characteristics upon passaging.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/  
Examiner, Art Unit 1633